REMARKS

Applicant acknowledges receipt of the Office Action dated December 17, 2002. Claims 1, 2, 6, 54, and 59 have been amended in response to this action. Claims 8, 50-53, 61, and 103-106 have been cancelled. Claims 7, 9-49, 60, and 62-102 have been withdrawn from consideration. Claims 107-115 are new. Reconsideration and further examination of the claims is respectfully requested.

It is known in the art to use formulations such as Benadryl to treat allergies. Besides the antihistamine diphenhydramine HCL, pseudoephrine HCL may be used as a decongestant, along with acetominophen or another anti-inflammatory pharmaceutical for headache pain. The current invention substitutes an herbal anti-inflammatory for the anti-inflammatory pharmaceutical.

The examiner rejected Claims 1-4, 6, 8, 50-57, 59, 61, and 103-106 under 35 USC 102(b) as being clearly anticipated by Martin, which teaches a composition including bromelain, a decongestant, and an antihistamine. Independent claims 1 and 54 have been amended so as to exclude the enzyme bromelain from the group of anti-inflammatory neutraceuticals. Further, claims 1 and 54 have been amended to exclude the presence of any anti-inflammatory agents other than the specified nutraceuticals. Thus, anti-inflammatory pharmaceuticals are excluded from the composition. This allows the present composition to provide effective anti-inflammatory activity without causing certain side effects noted with anti-inflammatory pharmaceuticals.

The examiner rejected Claims 3, 5, 56, and 58 under 35 USC 103(a) over Martin, in view of Wiersma, Hamel, Ayer, and Weinstein. Martin teaches a composition including bromelain, a decongestant, and an antihistamine. The examiner asserts that Wiersma, Hamel, Ayer, and Weinstein each teach combinations of decongestants and antihistamines which one of ordinary skill in the art would readily be able to substitute for the combination used in Martin. However, Martin teaches the use of the enzyme bromelain as an anti-inflammatory, and Claim 1, as amended, restricts the choice of anti-inflammatory neutraceuticals to at least one bioflavonoid, at least one herbal extract containing at least one bioflavonoid, curcumin, herbal extracts containing curcumin, and stinging nettle and extracts thereof. Wiersma, Hamel, Ayer, and Weinstein fail to provide any teaching that would indicate to one of ordinary skill in the art that it is beneficial to add a nutraceutical as recited in amended claim 1 to an antihistamine, a decongestant, or a mixture thereof. Martin teaches that bromelain is advantageous because it is a proteolytic agent that reduces the viscosity of respiratory secretions, not because of anti-inflammatory properties per se (Col. 2, ll. 12-24). Martin fails to provide a teaching that would indicate to one of ordinary skill in the art that substitution of a nutraceutical containing such non-proteolytic active ingredients as bioflavonoids, curcumin, and/or stinging nettle (active ingredient: sitosterol) for the proteolytic enzyme bromelain would be advantageous.

The examiner rejected Claims 1-6, 8, 50-59, 61, and 103-106 under 35 USC 103(a) by the examiner Wiersma, Hamel, Ayer, or Weinstein, combined with Armstrong. The examiner asserts that Wiersma, Hamel, Ayer, and Weinstein each teach combinations of decongestants and antihistamines. Armstrong teaches an allergy

composition comprising stinging nettle. The examiner asserts that it would be obvious to combine the composition of Armstrong with a combination of decongestants and antihistamines taught by Wiersma, Hamel, Ayer, or Weinstein. However, Armstrong teaches that his composition functions by providing the essential ingredient Vitamin B12, with stinging nettle as an optional additive. Armstrong states that (Col. 1, ll. 48-57):

> The mechanism of action for Vitamin B12 in IgE-mediated allergic diseases, such as allergic rhinitis and asthma, may involve the maturation of certain immune system cells including polynucleated cells, natural killer (NK) cells, and CD8+ cells. The CD8+ cell is an immune system T lymphocyte believed to "put the brakes on" the immune system, making the allergy patient less sensitive to allergens such as pollen, cats, and mold. Typically, allergic individuals have numbers of the CD8+ suppressor cells that are low relative to CD4 aggressor cells.

Armstrong fails to provide any teaching that would lead one of ordinary skill in the art to the conclusion that stinging nettle aids in the maturation of immune system cells in the absence of Vitamin B12. Further, it fails to offer any discussion of the benefits to be gained from substituting stinging nettle for an antiinflammatory, or even to teach that stinging nettle is an antiinflammatory agent.

Again, it is known in the art to use formulations containing an antihistamine, a decongestant, and an anti-inflammatory pharmaceutical for headache pain. The current invention substitutes an herbal anti-inflammatory for the anti-inflammatory pharmaceutical. This substitution provides several distinct and non-obvious advantages over the use of an NSAID anti-inflammatory.

First, one major benefit of substituting an herbal anti-inflammatory agent for an NSAID is that it allows the patient to avoid a significant but inadequately appreciated side effect of NSAIDs. Espey et al., in FERTILITY AND STERILITY, 38(2):238-247,

1982 (Abstract included in "NSAIDs, Aspirin & Infertility," attached hereto [http://www.fertilityplus.org/faq/nsaids.html]), shows, in a study on rabbits, that "ovulation was inhibited by the nonsteroidal antiinflammatory agents diclofenac, indomethacin, fenoprofen, niflumate, tolmetin, phenylbutazone, naproxen, meclofenamate, ibuprofen, and flufenamate." Acetaminophen also led to inhibition of ovulation. Admittedly, this is a study on rabbits and it is questionable whether data on rabbits can be directly translated to humans; however, further data indicates that inhibition of ovulation also applies to humans. Akil et al., in Br J Rheumatol 35: 1, 76-8, Jan, 1996 (Abstract included in "NSAIDs, Aspirin & Infertility," attached hereto [http://www.fertilityplus.org/faq/nsaids.html]) states (emphasis added):

> We report three cases of infertility where the cause may have been NSAID-induced 'luteinized unruptured follicle' syndrome. This phenomenon is well recognized in obstetric circles, and we would like to bring it to the attention of rheumatologists since it is *not documented* in the rheumatological literature.

Further abstracts on this subject are attached hereto. For this reason, women of childbearing years can substantially benefit from an allergy medication that removes anti-inflammatory pharmaceuticals. However, such preparations typically include no ingredient for management of discomfort caused by inflammation. This may cause patients to supplement the allergy medication with anti-inflammatory drugs, losing the benefit created by removal of these drugs in the first place.

As an alternative to NSAIDs, an allergy patient could use inhaled corticosteroids as antiinflammatories. However, this also has potential side effects. Most significantly, it can cause reduced levels of Dehydroepiandrosterone (DHEA). Low levels of DHEA have been associated with depression and reduced immunity (See

http://www.mycustompak.com/healthNotes/Supp/DHEA.htm, attached hereto.). It can also cause reduced calcium absorption.

Substitution of one or more herbal antiinflammatories for an NSAID or a corticosteroid is not directly taught by any of the references cited by the examiner. Further, the use of herbal antiinflammatories to replace NSAIDs having reproductive side effects is not taught in any of the cited references.

The examiner indicated that a reference teaching a preparation for teaching treatment of breast cancer patients with a preparation containing stinging nettle might be cited against the current invention in the future. Until such a rejection is made, a detailed response cannot be provided; however, the current invention is intended for use in treatment of allergy. A person of ordinary skill in the art would not look to cancer therapies to treat common allergies. Further, teachings in the current art exist indicate that it is not advisable to remove NSAIDs from a medication for use by breast cancer patients. Schapira et al., in International Journal of Oncology, 6(2):433-435 1995 (abstract attached hereto), report:

> ....[I]ngestion of NSAIDs was inversely associated with the size of the primary tumor, the lymph node status, and the number of involved axillary nodes. Ingestion of NSAIDs may impact favorably on factors that determine the prognosis and clinical outcome of women with breast cancer.

Similarly, Harris et al., in International journal of oncology , 6(1):71-73 1995 (abstract attached hereto), report:

> Breast cancer rates decreased by about 50% with regular ibuprofen intake ($p<0.01$), and by about 40% with regular aspirin intake ($p<0.05$). The results suggest that specific NSAIDs may be effective chemopreventive agents against breast cancer.

Abstracts of the cited articles are attached hereto. In view of this research, a person of ordinary skill in the art would not be motivated to replace NSAIDs with stinging nettle in medications used for treating cancer patients. The current invention was not, however, designed as a cancer therapy or intended for use in the treatment of cancer. Rather, the substitution of stinging nettle for NSAIDs in allergy preparations benefits women of childbearing years who are concerned with fertility issues.

With regard to the newly presented independent claims, each claim relates to a composition comprising a pharmaceutical, an anti-inflammatory neutraceutical, and a second neutraceutical, which may be a liver protectant, an anti-oxidant, or an immune booster. These neutraceuticals have been added because patients frequently take NSAIDs in conjunction with allergy medications. However, in excessive amounts, NSAIDs can cause liver inflammation. Thus, the inventive compositions both provide nutraceutical treatment for pain and inflammation to such patients without increasing the likelihood that the patients will suffer toxic effects from an overdose of NSAIDs; and they provide nutraceuticals which are therapeutically effective in the treatment of liver disorders. The liver protectant milk thistle is well known for its hepatoprotective properties. Plant immunostimulants, such as Echinacea, have been shown to improve phagocytosis of erythrocytes in liver tissue (Arzneimittel Forschung Drug research, 35(9):1437-1439, 1985; abstract attached):

> "...the influence of an immune stimulant of plant origin on the activity of Kupffer cells was tested. It was shown that the phagocytosis of erythrocytes was improved significantly by the single extracts and the combination of this. The extract of thuja occidentalis had the most prominent effect on the first phase of phagocytosis, whereas the extract of echinacea purpurea dominantly influenced the phagocytosis dependent metabolism."

Similarly, antioxidants modulate the toxic effects of free radicals on the liver, leading Halim et al. to conclude (ANNALS OF CLINICAL BIOCHEMISTRY , 34 (Pt 6)():656-663 1997; abstract attached) that "Administration of antioxidants could play an important role in prophylaxis against lipid peroxidation and consequently liver fibrosis caused by free radicals."

Further, it is well known that stinging nettle is effective in treatment of benign prostatic hyperplasia, as noted by Hryb et al., Planta Med., 61(1): 31-2 (1995) (abstract attached hereto). It is also well known that antihistamines can exacerbate prostate enlargement. Similarly, antihistamines can cause urinary retention, while stinging nettle helps to relieve urinary disorders. Thus, the neutraceutical ingredient not only acts as an anti-inflammatory, it helps to relieve potentially harmful side effects of the antihistaminic drugs.

While we believe that the instant amendment places the claims in condition for allowance, should the Examiner have any further comments or suggestions, it is respectfully requested that the Examiner telephone the undersigned attorney in order to expeditiously resolve any outstanding issues.

In the event that the fees submitted prove to be insufficient in connection with the filing of this paper, please charge our deposit account number 50-0578 and please credit any excess fees to such Deposit Account.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Please cancel claims 8, 50- 53, 61, and 103-106.

Please amend claims 1, 6, 54, and 59 as follows:

1. (amended) A medicinal composition, comprising:

a pharmaceutical, where said pharmaceutical is an antihistamine; and

[a nutraceutical] one anti-inflammatory agent, said anti-inflammatory agent being a neutraceutical selected from the group consisting of at least one bioflavonoid, at least one herbal extract containing at least one bioflavonoid, curcumin, herbal extracts containing curcumin, stinging nettle and extracts thereof, and mixtures thereof; and

a pharmaceutically acceptable medium[base];

where at least one of the pharmaceutical and the nutraceutical treats at least one ailment or symptom thereof caused by an immune response.

2. (amended) A composition according to claim 1, wherein the immune response is an immune response to a virus, a microorganism, or an atmospheric pollutant or allergen, and where said one anti-inflammatory agent is the only anti-inflammatory agent present in the composition.

6. (amended) A composition according to claim 2, [wherein said nutraceutical is selected from a group consisting of immune boosters, anti-inflammatory nutraceuticals, antioxidants, a liver protectant, and mixtures thereof] further comprising a nutraceutical

selected from the group consisting of an immune booster, an antioxidant, a liver protectant, or a mixture thereof.

54. (amended) 54. A method of treating a patient suffering from an ailment or symptom thereof caused by an immune response, comprising the step of administering a medicinal composition to the patient, wherein said medicinal composition comprises:

a pharmaceutical, where said pharmaceutical is an antihistamine; and

[a nutraceutical] one anti-inflammatory agent, said anti-inflammatory agent being a neutraceutical selected from the group consisting of at least one bioflavonoid, at least one herbal extract containing at least one bioflavonoid, curcumin, herbal extracts containing curcumin, stinging nettle and extracts thereof, and mixtures thereof; and

a pharmaceutically acceptable medium[base];

where at least one of the pharmaceutical and the nutraceutical treats at least one ailment or symptom thereof caused by an immune response;

where said one anti-inflammatory agent is the only anti-inflammatory agent present in the composition.

59. (amended) A method according to claim 55 [wherein said nutraceutical is selected from a group consisting of immune boosters, anti-inflammatory nutraceuticals, antioxidants, a liver protectant, and mixtures thereof] further comprising a nutraceutical selected from the group consisting of an immune booster, an antioxidant, a liver protectant, or a mixture thereof.

Please add the following claims 107-115:

107. (new) A medicinal composition, comprising:

a pharmaceutical, where said pharmaceutical is an antihistamine; and

one anti-inflammatory agent, said anti-inflammatory agent being a neutraceutical selected from a group consisting of at least one bioflavonoid, at least one herbal extract containing at least one bioflavonoid, curcumin, herbal extracts containing curcumin, stinging nettle and extracts thereof, and mixtures thereof;

a liver protectant; and

a pharmaceutically acceptable medium;

where at least one of the pharmaceutical and the nutraceutical treats at least one ailment or symptom thereof caused by an immune response;

where said one anti-inflammatory agent is the only anti-inflammatory agent present in the composition.

108. (new) A medicinal composition according to claim 107, further comprising a decongestant.

109. (new) A medicinal composition according to claim 107, wherein the liver protectant is milk thistle.

110. (new) A medicinal composition, comprising:

a pharmaceutical, where said pharmaceutical is an antihistamine; and

one anti-inflammatory agent, said anti-inflammatory agent a neutraceutical selected from a group consisting of at least one bioflavonoid, at least one herbal extract

containing at least one bioflavonoid, curcumin, herbal extracts containing curcumin, stinging nettle and extracts thereof, and mixtures thereof;

an immune booster; and

a pharmaceutically acceptable medium;

where at least one of the pharmaceutical and the nutraceutical treats at least one ailment or symptom thereof caused by an immune response;

where said one anti-inflammatory agent is the only anti-inflammatory agent present in the composition.

111. (new) A medicinal composition according to claim 110, wherein the immune booster is selected from a group consisting of zinc and effective salts thereof, at least one herb selected from a group consisting of herbs of the genus *Echinacea*, at least one herb selected from a group consisting of herbs of the genus *Sambucus*, Goldenseal and mixtures thereof.

112. (new) A medicinal composition according to claim 110, further comprising a decongestant.

113. (new) A medicinal composition, comprising:

a pharmaceutical, where said pharmaceutical is an antihistamine; and

one anti-inflammatory agent, said anti-inflammatory agent a neutraceutical selected from a group consisting of at least one bioflavonoid, at least one herbal extract containing at least one bioflavonoid, curcumin, herbal extracts containing curcumin, stinging nettle and extracts thereof, and mixtures thereof;

an anti-oxidant; and

a pharmaceutically acceptable medium;

where at least one of the pharmaceutical and the nutraceutical treats at least one ailment or symptom thereof caused by an immune response

where said one anti-inflammatory agent is the only anti-inflammatory agent present in the composition.

114. (new) A medicinal composition according to claim 113, further comprising a decongestant.

115. (new) A medicinal composition according to claim 113, wherein the anti-oxidant is selected from a group consisting of at least one bioflavonoid, at least one herbal extract containing at least one bioflavonoid, ascorbic acid and pharmaceutically effective salts and derivatives thereof, garlic and extracts thereof, green tea and its extracts, at least one herb selected from a group consisting of herbs from the genus *Astragalus*, and combinations thereof.